**Remarks/Arguments:**

**Preliminary Matters:**

Claims 1 and 3-51 are pending. Of these, claims 9, 12-16, 18-29, 34-46 and 48-50 have been withdrawn from consideration in accordance with a restriction requirement. Claims 1, 3-8, 10, 11, 17, 30-33, 47, and 51 stand rejected by the final Office Action dated November 9, 2004. The Applicants respectfully traverse the rejections and offer the following remarks.

**Rejection under 35 U.S.C. § 103 -- Heyn in View of Marianne**

Claims 1, 3-8, 10, 11, 17, 30, 32, 47 and 51 stand rejected under 35 U.S.C. § 103(a) as anticipated by U.S. Patent No. 5,201,757 to Heyn et al. (Heyn) in view of U.S. Patent No. 6,042,589 to Marianne (Marianne). Applicants respectfully traverse this rejection and respectfully submit that these claims are patentable over Heyn in view of Marianne for the reasons set forth below.

Independent claims 1 and 47, as amended, recite at least one feature that is neither disclosed nor suggested by Heyn or Marianne taken singly or in combination, namely:

> . . . anchoring means in at least one of the retrograde portion or the anterograde portion for anchoring the *proximal end* of the endoluminal device *in the body lumen* to minimize relative axial movement between the proximal end of the device and the body lumen during deployment of the device *from the device proximal end toward the device distal end*. (Claim 1).

> . . . an inflatable balloon mounted radially inside the retrograde portion for anchoring the *proximal end* of the endoluminal device *in the body lumen* to minimize relative axial movement between the proximal end of the device and the body lumen *during deployment of the device from the device proximal end toward the device distal end.* (Claim 47)

The italicized text above highlight patentable features of the present invention as claimed, namely that the claimed introducer comprises an anchoring means or inflatable balloon for anchoring the *proximal* end of the endoluminal device *in the body lumen* during deployment of the device *from the device proximal end toward the device distal end*. One aspect of applicants' invention comprises a structure for deploying a prosthesis from its proximal end to its distal end. *See* page 3, lines 18-27 of the originally filed specification. This feature is advantageous in applications where accurate placement of the proximal end of the stent is desirable for successful treatment. *See* page 2, line 27 to page 4, line 6 of the originally filed specification. The ability to control the proximal terminus of a prosthesis component is of

particular use in branched lumen anatomies such as the intersection between the abdominal aorta - iliac arteries.

In contrast, the devices of both Heyn and Marianne, although intended to fix a prosthesis during deployment, are not configured to anchor the *proximal* end of the prosthesis in the body lumen during a proximal-end-first delivery (i.e. reverse delivery) as disclosed and claimed in the instant application. A review of Heyn reveals that the device it discloses is clearly configured to deploy a prosthesis starting from its central or medial region. *See* Heyn figures. Likewise, the device disclosed by Marianne is not configured for proximal-end-first deployment because it is clearly designed for distal-end-first deployment. *See* Marianne at Figures 1-6 and column 3 lines 1-15.

Accordingly, neither the device disclosed by Heyn or Marianne could be used to precisely place the proximal end of the device in the body lumen before full deployment of the prosthesis, which is an advantage of the Applicants' claimed invention. Because Heyn opens from the middle, the device disclosed by Heyn can only be used to deploy the device from the middle to the ends, and offers no means for anchoring the device in the body lumen during deployment. Therefore, the user can only estimate where the proximal end will actually land. The device disclosed by Marianne is structured to retract the sheath from the distal end to the proximal end and is adapted to release the proximal end last. Thus, the user must place the proximal end of the device by first partially deploying the distal end of the device, anchoring the proximal end against sheath 16, and then moving the partially deployed device to the desired position before releasing the proximal end. *See* Marianne, column 3, lines 5-41. By contrast, Applicants claimed invention allows the user to deploy and anchor the proximal end first in the precise location desired, and then deploy the rest of the stent from the proximal to the distal end.

In the Response to Arguments, the Office Action asserts that the device disclosed by Marianne "is clearly capable of performing the function of anchoring a stent in the body lumen during deployment" and points to Figures 4 and 5 in support of this assertion. The applicants respectfully point out that Figures 4 and 5 of Marianne merely depict an inflated balloon inside a fully deployed stent. The applicants have specifically claimed means for anchoring the device in the body lumen *during* deployment of the device from its proximal end to its distal end. The structure of Marianne does not allow deployment of the device from its proximal end to its distal end at all, let alone anchoring any portion of the device in the body lumen while the rest of the device is being deployed. Marianne only discloses using a balloon to anchor the proximal end of the stent to the sheath *after* the distal end of the stent has been partially deployed *from its distal end to its proximal end* (column 3, lines 5-41), or to cure a stenosis in a lumen after the

stent has been fully deployed (column 3, lines 45-54). Accordingly, Marianne fails to disclose Applicants' claimed invention.

Because both claims 1 and 47 include limitations that are neither disclosed nor suggested by Heyn or Marianne, alone or in combination, these claims should be allowed, and claims 3-8, 10, 11, 17, 30, 32, and 51, which are dependent upon claim 1, should also be allowed at least as being dependent upon an allowable base claim.

**Rejection under 35 U.S.C. § 103 -- Heyn in View of Euteneuer**

Claims 31 and 33 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Heyn in view of U.S. Patent No. 5,445,646 to Euteneuer et al. (Euteneuer). Applicants respectfully traverse this rejection and respectfully submit that these claims are patentable over Heyn in view of Euteneuer for the reasons set forth below.

Euteneuer is cited in the Office Action only for its teaching of the anterograde sheath covering more than the retrograde sheath and for overlapping the two sheaths. Both Euteneuer and Heyn fail to teach or suggest, either singly or in combination, means for anchoring the proximal end of the endoluminal device *in the body lumen* to minimize relative axial movement between the proximal end of the device and the body lumen during deployment of the device *from the device proximal end toward the device distal end*, as claimed by Applicants. Both references disclose an apparatus that can be used to anchor the ends of the respective prostheses inside a respective sheath and/or against a central core during deployment, but not for anchoring the proximal end *in the body lumen* during deployment from the proximal end to the distal end. By contrast, Applicants disclose and claim an apparatus that is adapted to anchor the device *in the body lumen* during deployment from the proximal end toward the distal end. *See, e.g.*, Figs. 5A and 5C in the application as filed, showing the proximal end anchored in the body lumen as the device is being deployed from the proximal end toward the distal end.

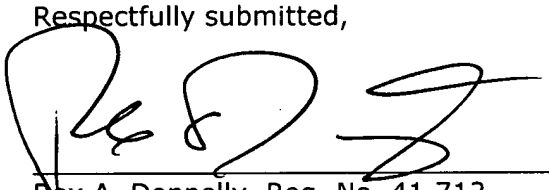
Although Euteneuer discloses in column 7, lines 64-65 that the stent can be "deployed starting from the proximal end of the stent," Euteneuer nowhere discloses means for anchoring the proximal end *in the body lumen* during such a deployment step. Rather, Euteneuer discloses only the use of water soluble bands 18, 60, or 62 for anchoring portions of the prosthesis to the central core until the bands dissolve, or the use of no such bands, in which case no anchoring is provided at all.

Thus, because claim 1 includes limitations that are neither disclosed nor suggested by Heyn or Euteneuer, alone or in combination, claims 31 and 33, which are dependent upon claim 1, should also be allowed.

**Conclusion:**

In view of the points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested. As a number of withdrawn claims are also dependent from allowable claims, the applicants further request allowance of such withdrawn claims as well. Should the Examiner still believe that any the claims are not allowable for any reason, Applicants respectfully request a telephone interview to further discuss the merits of this application.

Respectfully submitted,



Rex A. Donnelly, Reg. No. 41,712
Phillip E. Gonzalez, Reg. No. 55,213
Attorneys for Applicants

RAD/peg

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☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

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